



UNITED STATES PATENT AND TRADEMARK OFFICE

ms

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,808	03/15/2000	Athanasius A Anagnostou	5218-39C	9764
20792 7590 11/28/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/525,808

Applicant(s)

ANAGNOSTOU ET AL.

Examiner

Christopher H. Yaen

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,22,31-33,42 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,22,31-33,42,44 and 47 is/are rejected.
- 7) ☒ Claim(s) 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/26/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Re: Anagnostou et al

The amendment filed 10/26/2007 is acknowledged and entered into the record. Accordingly, claims 1-15, 17-21, 23-30, 34-41, and 43 are canceled without prejudice or disclaimer, and claims 44-47 are newly added.

Claims 16, 22, 31-33, 42, and 44-47 are pending and examined on the merits.

Information Disclosure Statement

The Information Disclosure Statement filed on 10/26/2007 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 16,22,33,42, and now newly added claim 47 under 35 USC § 103(a) is maintained for the reasons of record. Applicant's arguments are substantially similar to those previously argued and rebutted in prior office actions. In this amendment, applicant primarily argues the new limitation of 700-2000 U/kg as not being suggested and taught in the prior art. However, claims 16,22,33,42, and 47 do not recite these new limitations and therefore the rejection is maintained. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

NEW REJECTIONS

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 31-32, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claims 31-32. and c44 have been amended or newly added to include the limitation of administering an endothelial protecting amount of erythropoietin (herein EPO) in a dose range of 750-2000 Units/kg. Applicant points to page 12 for support of the newly added limitation. It appears that the claim and the specification are describing two different end results. In the claims, the methods are drawn to the reduction of endothelial cell damage caused by chemotherapeutics by administering a “endothelial protecting amount” EPO, which operates by a mechanism of reducing or preventing the suppression of growth caused by the administration of chemotherapeutics. The specification teaches that “EPO is administered in an **endothelial-inhibiting amount** which may range from about 750 U/kg to about 2,000 U/kg.” (Emphasis added). The amount claimed is for an amount used in the inhibition of endothelial cells. This is clearly distinguished from the administration of EPO for the purpose of protecting, wherein the administration of EPO in the amount of 100-200 U/kg is used (see pg 12, lines 26-37, for example). Therefore, the use of a dosage of 700-2000U/kg is not supported in the specification as filed for the purposes of treating endothelial injury (i.e. promoting endothelial cell growth after chemotherapeutic administration) as claimed. Applicant is invited to point to clear support for the claimed limitation by pointing to specific page and line number

Claim Rejections Reinstated - 35 USC § 102

The rejection of claims 16 and 33 under 35 USC § 102(b) as being anticipated by Silvestris *et al* (Ann. Hematol 1995 June; 70(6):313-318, previously cited) is maintained

for the reasons of record. This rejection was previously withdrawn in view of the amendments filed 6/27/2006. The claims as currently amended are anticipated by the cited reference because EPO was administered to patients undergoing second induction chemotherapy. Moreover, the reference teaches that the dosage of EPO was between 100U/kg and 300 U/kg. The rejection is maintained.

Claim Objections

Claims 45 and 46 are objected to because of the following informalities: Claim depend on a previously canceled claim (i.e. claims depend on claim 1 which is now canceled). Appropriate correction is required.

Conclusion

No claims are allowed.

This is a RCE of applicant's earlier Application No. 09/525808. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:
09/525,808
Art Unit: 1643

Page 7

/Christopher Yaen/
Primary Examiner
Art Unit 1643
November 15, 2007